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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,517	09/16/2003	Sang Yup Lee	Q77445	2292

23373 7590 09/26/2006

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EXAMINER	
PROUTY, REBECCA E	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,517	LEE ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-11,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 6-11, 15, 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 3, 5, and 12-14 have been canceled. Claims 1, 2, 4, 6-11 and newly presented claims 15 and 16 are still at issue and are present for examination.

Applicants' arguments filed on 6/26/06, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 recites a vector comprising both the plasmid pAC104CysK and the plasmid pEDIL-12p40. Nowhere in the specification as filed is such a vector composed of these two specific vectors described. The specification describes bacteria cotransformed with both vectors and vectors generically including both a cysK gene and a IL-12p40 gene but does not describe a single vector including all sequences of both

specific plasmids as now recited. This is a new matter rejection.

Claim 10 and new claim 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is explained in the previous Office Action.

Applicants argue that plasmid pAC104CysK as shown in Fig. 2 and plasmid pEDlL-12p40 as shown in Fig. 3 are constructed from known vectors and sequences and thus the specification is enabled as filed. However, while as stated by applicants *E. coli* BL21(DE3), *E. coli* XL1-blue, plasmid pACYC184, and plasmid pUC18/p40 are commercially available, constructing the plasmid pAC104CysK also requires the plasmid p10499A and constructing the plasmid pEDlL-12p40 requires the leptin expression vector of Jeong and Lee, (Appl. Environ. Microbiol., 65:3027-32, 1999) neither of which is fully disclosed in the specification or shown to be publicly available. As such these vectors cannot be completely constructed using the instructions in the specification.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 6-9, 11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez et al. and Lamouse-Smith et al. in view of Martens et al., Swiss-Prot Accession No. P29460, Hatamoto et al. (JP 09/009982) and Koonin et al. The rejection is explained in the previous Office Action.

Applicants argue that the amount of cysteine in a host cell is not a main factor for increasing production of serine-rich protein but rather, metabolic burden in the synthetic pathway of serine family amino acids in the early stage of serine-rich protein production prevents the synthesis of serine-rich proteins. However, this is not persuasive, because both Ramirez

et al. and Lamouse-Smith et al. teach that recombinant protein production in *E. coli* can be improved by increasing the available levels of amino acids present in a recombinant protein in levels substantially above the levels of that amino acid in *E. coli* proteins and the art clearly suggests that cysteine is such an amino acid in IL-12 p40 such that a skilled artisan would believe that increasing the amount of cysteine would enhance production of IL-12 p40. Applicants argue that the cysK gene is associated with cysteine synthetic pathway but that it cannot increase cysteine production and that the cysE gene is the main factor for increasing cysteine production. However, this is not persuasive because Hamamoto et al. clearly teach methods of enhancing cysteine production in *E. coli* using the cysK gene. Applicants claims do not exclude the inclusion of the other genes disclosed by Hamamoto et al. as also useful for enhancing cysteine production. Therefore, applicants arguments with regard to the lack of enhancement of protein production as a result of cysE gene amplification is irrelevant as use of all genes disclosed by Hamamot et al. is included within the scope of applicants claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Prouty

REBECCA E. PROUTY
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